

# UNITED STATES, JEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO 6 FILING DATE 7/96	ANDERIRSTINAMED INVENTOR	s	ATTORNEY IDDEKET NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.
Of 746,169

Examiner No lan

Applicant(s)

Group Art Unit

1644

....The MAII ING DATE of this communication appears on the cover sheet beneath the correspondence address...

-The MAILING DATE of this communication appears on the cover si	neet beneaut the correspondence address-			
Period for Resp nse	7			
A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE MAILING DATE OF THIS COMMUNICATION.	MONTH(S) FROM THE			
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, I from the mailing date of this communication.</li> <li>If the period for response specified above is less than thirty (30) days, a response within the If NO period for response is specified above, such period shall, by default, expire SIX (6) MFF.</li> <li>Failure to respond within the set or extended period for response will, by statute, cause the</li> </ul>	e statutory minimum of thirty (30) days will be considered timely. ONTHS from the mailing date of this communication.			
Status				
Responsive to communication(s) filed on 16-27-97	·			
This action is FINAL.				
☐ Since this application is in condition for allowance except for formal matters accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 1 1; 453 O.				
Disp sition of Claims				
// Claim(s)/-20	is/are pending in the application.			
7 (Claim(s) 7-20 Of the above claim(s) 9-16 and 19-20	is/are withdrawn from consideration.			
□ Claim(s)	is/are allowed.			
# Claim(s) 1-8 and 17-18	is/are rejected.			
(Claim(s) 1-8 and 17-18	is/are objected to.			
□ Claim(s)				
	requirement.			
Application Papers	_			
<ul> <li>□ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-94</li> <li>□ The proposed drawing correction, filed on is □ appro</li> </ul>				
☐ The drawing(s) filed on				
☐ The drawing(s) filed on	mier.			
☐ The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. § 119 (a)-(d)				
Aknowledgment is made of a claim for foreign priority under 35 U.S.C. § 1  All Some* None of the CERTIFIED copies of the priority docume received.  received in Application No. (Series Code/Serial Number).  received in this national stage application from the International Bureau (	ents have been			
*Certified copies not received:	·			
Attachment(s)				
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).	☐ Interview Summary, PTO-413			
☐ Notice of References Cited, PTO-892	☐ Notice of Informal Patent Application, PTO-152			
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	□ Other			
Office Action Summar	y			

U. S. Patent and Trademark Office PTO-326 (Rev. 3-97)

\*U.S. GPO: 1997-417-381/62710

Part of Paper No. \_\_

#### Serial Number 08/716,169 Art Unit: 1644

#### Part III DETAILED ACTION

- 1. This application is a 371 of PCT/NL95/00108.
- 2. Claims 1-20 are pending.
- 3. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.
- 4. Applicant's election with traverse of Group I, claims 1-8 and 17-18 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that according to 37 CFR 1.475, unity of invention is found if claims are drawn to a product and process specially adapted for the manufacture of said product. This is not found persuasive because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The protein as claimed in group I was publicly disclosed prior to Applicant's invention in the Journal of Immunology, Volume 141: 2749-2754 in October of 1988.

The requirement is still deemed proper and is therefore made  $\ensuremath{\mathsf{FINAL}}$  .

5. Claims 1-8 and 17 and 18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons supplied in Paper No. 14.

Applicant's arguments filed 10-27-97 have been fully considered but are not found persuasive.

Applicant argues that sequence identity is a term well known in the art as evidenced by a internet search on phrase "sequence identity" done by Applicant and supplied to the Examiner in Applicant's response.

However, since different algorithm used to calculate sequence identity amongst sequences can produce different results, for a claims metes and bounds to be understood, Applicant would be required to identify which specific algorithm, as supported by Applicant's original specification, was used to determine sequence identity in the claimed subject matter.

Applicant also argues that claim 7 does not lack antecedent basis now that it depends from base claim 1. Further Applicant argues that claim 7 contemplates a microbial peptide having two T-cell epitopes, one of which has substantial identity with the mammalian stress protein, the other not having sufficient homology with the mammalian stress T-cell epitope.

However, claim 7 does not delineate between two different T cell epitopes. If Applicant amended their claim to describe the

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intention of the claimed subject as argues by Applicant above, the 112: 2nd paragraph rejection would be removed.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 and 17-18 stand rejected under 35 U.S.C. \$ 102(b) as being anticipated by Oftung et al. (AS), of record, for reasons supplied in Paper No. 15.

Applicant's arguments filed 10-27-97 have been fully considered but are not found persuasive.

Applicant argues that the peptide taught by Oftung et al., has practically zero T-cell response and therefore cannot read on the claims.

However, Applicant are drawn to microbial peptides which share sequence to mammalian T-cell epitopes, not microbial T-cell epitopes. Applicant's argument that the peptide taught by Offung et al., has practically zero T-cell response and therefore cannot read on the claims is an argument of a functional limitation that is not in the claims.

7. Claims 1-4 and 17-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent 262,710 (AL), of record for reasons supplied in Paper No. 15.

Applicant's arguments filed 10-27-97 have been fully considered but are not found persuasive.

Applicant argues that the '710 patent peptide is a 70mer, while Applicants claims are directed to specific 5-30mers. Furthermore, Applicant argues that 5-30mer peptides provide superior results as compared to the complete hsp65 protein and large fragments thereof that do not comply with the claimed selection criteria.

However, in claim 1, the term comprising 5-30mer, opens the peptide upto the complete microbial protein minus 1 amino acid because the claim is drawn to a part of the microbial protein. Therefore the 70mer protein taught by the '710 patent meets the claim limitation. In addition, unexpected superior results do not overcome 35 U.S.C. 102(b) anticipation rejections.

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### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. \$ 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103@ and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 8 stands rejected under 35 U.S.C. § 103 as being unpatentable over Oftung et al., (AS), or European Patent 262,710 (AL) in view of U.S. Patent 5,643,873 (A).

Applicant's arguments filed 10-27-97 have been fully considered but are not found persuasive.

Applicant argues that since the rejections based upon the Oftung et al., or  $^{1}$ 10 patent have been obviated the rejection of claim 8 under 35 U.S.C. 103 has also been obviated.

Applicant is directed to the Examiner's arguments supra.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period,

then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to  $37\,$  CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.
- 11. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick Nolan, Ph.D. June 24, 1998 Christopher Eisenschenk, Ph.D., J.D. Primary Examiner June 24, 1998